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| Total hCG - Qualitative & Quantitative | | | | | | |
| ADVIA Centaur®, ADVIA Centaur® XP, and ADVIA Centaur® XPT Systems | | | | | | |
| Prepared by: | Debra Napert MT (ASCP) | | | Adopted: |  | |
| Approved by: |  | | | Date: |  | |
| The medical or laboratory director or the director’s designee should review all copies of this procedure. | | | | | | |
| Reviewer | | Date | Reviewer | | | Date |
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| Revisions | | Date | Authorized by | | |  |
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Lifespan AMC – Department of Pathology

The Miriam Hospital \_\_\_ \_\_\_ Rhode Island Hospital

164 Summit Avenue 593 Eddy Street

Providence, Rhode Island 02906 Providence, Rhode Island 02903

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| Total hCG | | | | |
| **Attributes for:** | Human chorionic gonadotropin | **Analyzer:** | ADVIA Centaur®  ADVIA Centaur® XP  ADVIA Centaur® XPT | |
| Principles of the Procedure | | | | |
| The ADVIA Centaur Total hCG (ThCG) assay is a two-site sandwich immunoassay using direct chemiluminometric technology, which uses constant amounts of two antibodies. The first antibody, in the Lite Reagent, is a polyclonal goat anti-hCG antibody that has been affinity purified and labeled with acridinium ester. The second antibody, in the Solid Phase, is a purified monoclonal mouse anti-hCG antibody, which is covalently coupled to paramagnetic particles. These two antibodies are specific for different epitopes that are present on both the free ß-subunit and the ß-subunit of intact hCG. | | | | |
| Intended Use | | | | |
| For *in vitro* diagnostic use in the quantitative determination of human chorionic gonadotropin (hCG) in serum using the ADVIA Centaur®, ADVIA Centaur XP, and ADVIA Centaur XPT systems. The results obtained from hCG specimens are used as an aid in the assessment of pregnancy status. This assay detects the intact hCG molecule and free beta-subunits of the hCG molecule.  This method will be used for both qualitative and quantitative hCG orders received. Results will be reported based on physician orders. | | | | |
| Specimen Types | | | | |
| Serum Test Codes **QBHCG:** Quantitative Assay  **PREG:**  Qualitative Assay | | | | |
| Specimen Stability | | | | |
| * Keep tubes stoppered and upright at all times. * Do not use samples that have been stored at room temperature for longer than 8 hours. * Unspun whole blood samples are stable for 24 hours. * Tightly cap, spin and refrigerate specimens at 2–8°C if the assay is not completed within 8 hours. * Add on testing may be performed on refrigerated specimens up to 7 days. | | | | |
| Minimum Sample Volume | | | | |
| 50 μL | | | | |
| Specimen Rejection Criteria The sample must be properly labeled with the minimum of the patient’s name and date of birth. For more information on the acceptability of samples, see “Protocol for Unacceptable Samples” in the Administrative Manual and Quality Control Procedures. | | | | |
| Preparing the Reagents | | | | |
| All reagents are liquid and ready to use.  Mix all primary reagent packs by hand before loading them onto the system. Visually inspect the bottom of the reagent pack to ensure that all particles are dispersed and resuspended. | | | | |
| Storage and Stability | | | | |
| Store the reagents upright at 2–8°C.  Protect reagent packs from all heat and light sources. Reagent packs loaded on the system are protected from light. Store unused reagent packs at 2–8°C away from heat and light sources.  All reagents are stable at 2–8°C until the expiration date on the packaging.  The ADVIA Centaur Total hCG assay reagents are stable unopened until the expiration date on the carton or onboard the system for 21 days. | | | | |
| Calibrator Material | | | | |
| Calibrator B  Preparing Calibrators  Add 5 ml of reagent grade water into each calibrator vial using a volumetric or precision pipette.  Let the calibrators stand for 15-20 minutes at room temperature (20-30°C) to allow lyophilized material to dissolve.  Gently swirl and invert until homogeneous.  Reconstituted calibrators are stable 28 days at 2 - 8°C.  Dispense at least 1 ml of low and high calibrator into labeled sample cups.  Schedule a calibration and use the lot specific barcodes labels provided. The low calibrator must precede the high calibrator.  Use calibrator B to perform a two-point calibration every 28 days and:   * When changing lot numbers of primary reagent packs * When replacing some system components * When quality control results are repeatedly out of range | | | | |

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| Quality Control Material |
| Commercially available quality control materials. Use Biorad Lyphocheck Immunoassay Plus Control 1& 3 to monitor assay performance.  QC Frequency  Analyze at least two levels of quality control material on each day that samples are analyzed.  Analyze all levels of quality control material each time a two-point calibration is performed.  Troubleshooting Out-of-Range QC Values  If the quality control results do not fall within the Expected Values or within the laboratory’s established values, do not report results. Take the following actions:   * Verify that the materials are not expired. * Verify that required maintenance was performed. * Verify that the assay was performed according to the instructions for use. * Rerun the assay with fresh quality control samples. * If necessary, contact your local technical support provider or distributor for assistance.   Corrective Action  Patient test results must be repeated, and corrective action taken when QC results fall outside of acceptable limits. Refer to the Troubleshooting Out-of-Range QC Values section |

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| Interferences |
| High-Dose Hook Effect  Patient samples with high hCG levels can cause a paradoxical decrease in the RLUs (high-dose hook effect). In this assay, patient samples with hCG levels as high as 400,000 mIU/mL (IU/L) will assay greater than 1000 mIU/mL (IU/L).  Specificity  The cross-reactivity of the ADVIA Centaur Total hCG assay with TSH, LH, FSH, prolactin, and hGH was determined by adding these hormones to serum samples containing hCG. The level of hCG in the samples was then determined.    Interference testing was determined according to CLSI Document EP7-A2.  Other Limitations  There are many possible causes for these types of discordant results. Erroneous results may occur due to interference from identifiable serum constituents or patient-specific serum constituents.  **Erroneous results due to interference are repeatable over time.**  Persistent serum hCG results in the range of 10 to 100 mIU/mL (more typically 10 to 50 mIU/mL) over several months suggests that the patient’s blood may contain an interfering substance and produce erroneous results.  Identified sources of interference that have the potential to bind to and interfere with any component of the assay include:   * + plasma components (clotting factors)   + serum proteins (such as rheumatoid factor)   + heterophile and anti-animal antibodies (such as anti-mouse, anti-rabbit, anti-goat)   + anti-idiotype antibodies   Interference can also be caused by:   * + drugs and drug metabolites   + cross-reacting substances |
| Calculation of Results |
| The system reports serum hCG results in mIU/mL (common units) or IU/L (SI units), depending on the units defined when setting up the assay. The conversion formula is 1 mIU/mL = 1 IU/L.  Lifespan reports mIU/mL for Quantitative tests. |
| Analytical Measuring Range |
| 2.0–1000 mIU/mL Clinical Reportable Range 2.0 - >200,000 mIU/mL |
| Dilutions |
| The following information pertains to dilutions:   * Serum samples with hCG levels greater than 1000 mIU/mL (IU/L) must be diluted and retested to obtain accurate results. * Patient samples can be automatically diluted by the system or prepared manually. * For automatic dilutions, ensure that ADVIA Centaur ThCG Diluent is loaded and set the system parameters as follows:   Dilution point: ≤ 1000 mIU/mL (IU/L)  Dilution factor: 5, 10, 100, 200 are available. Lifespan analyzers are preset to perform a x200 dilution when the diluent is on board. The system automatically calculates the result using the preset dilution value of 200.  The maximum reportable value is 200,000 and values greater than that are reported as >200000. |
| Sensitivity |
| The ADVIA Centaur Total hCG assay measures hCG concentrations up to 1000 mIU/mL (IU/L) with a minimum detectable concentration (analytical sensitivity) of 2.0 mIU/mL (IU/L). Analytical sensitivity is defined as the concentration of hCG that corresponds to the RLUs that are two standard deviations greater than the mean RLUs of 20 replicate determinations of the Total hCG zero standard. |
| Expected Values |
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| Qualitative (PREG): Negative  Quantitative (QBHCG): ≤ 5 mIU/mL- Healthy nonpregnant females, males, and post-menopausal females |
| Critical Values |
| There are no critical values with this test. |
| Reporting |
| **QBHCG -** Quantitative values with Reported Interpretation  Reportable range : < 2.0 - >200,000 mIU/mL  Gestational Age Expected QBHCG values (mIU/ML)  0.2-1 week 5 - 50  1 - 2 weeks 50 - 500  2 - 3 weeks 100 - 5,000  3 - 4 weeks 500 - 10,000  4 - 5 weeks 1,000 - 50,000  5 - 6 weeks 10,000 - 100,000  6 - 8 weeks 15,000 - 200,000  2 - 3 months 10,000 - 100,000  **PREG -** Qualitative interpretations as follows:   1. hCG < 2.0 mIU/mL **is Negative** 2. hCG 2.0 - 39.0 mIU/mL is **Indeterminate**   The following comment will be reported with Indeterminate and Negative results:  *A Negative or Indeterminate result does not rule out pregnancy. A patient with a negative or Indeterminate result should be redrawn in two days and assayed again because hCG doubles every 48 hours.*   1. hCG >39 mIU/mL is **Positive**  Courtesy Call - (PREG) – All Positive results called to Emergency Dept |
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**Note** Appendices L1 and L3 of CLSI QMS02-A6, published 2/28/2013, guided the creation of this document.

Siemens document number: 10634917K\_eThCG\_XP\_EN